



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH  
WASHINGTON, DC 20460

OFFICE OF  
RESEARCH AND DEVELOPMENT

August 2, 2006

TO: Marie Lynn Miranda, Associate Research Professor, Duke University  
and Director, Children's Environmental Health Initiative

FROM: Nigel Fields, US EPA Project Officer

SUBJECT: Potential STAR Center grant —Southern Center on  
Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO)

Congratulations,

I am pleased to inform you that EPA's Office of Research and Development, National Center for Environmental Research (NCER) will be making a recommendation to the EPA Grants Administration Division (GAD) to fund your research proposal through our STAR Program. This is not an official notification of the award; only the Agency's Grants Administration Division can make the formal award and announcement. The purpose of this email is to request additional information regarding your proposal.

As your project officer, I will be preparing the necessary paperwork to process the funding request. In order to complete the funding package, I will need the information below from you as soon as possible. Anything you do not submit electronically, or anything that requires original signatures, needs to be sent via FedEx. EPA is still experiencing delays of up to a month with our regular mail system due to security checks and irradiation of mail.

Questions: First, I need to have you answer a few questions in order to update your proposal. Please e-mail your response to me. Do you anticipate any of the following situations associated with this grant award:

- 1) Any changes to your proposal, i.e., are personnel moving to other universities and such?
- 2) Any foreign travel?
- 3) Any federal employees on your grant?
- 4) Conducting workshops?
- 5) Human and/or animal subjects?
- 6) Development of questionnaires/and or surveys?

Grants Administration Division Number:

Your application will be assigned GAD number upon receipt of a sf424 application, and key contacts sheet (attached). Once assigned, please use this number on any correspondence you send to me, or anyone at EPA, as it makes it easier for us to locate your file. This is the number you will use as the grant/project number on forms you will need to complete, as well as on your annual and final reports, abstracts, etc.

### Abstract:

Please update/revise your abstract using the format contained in the attached file "NCER STAR GRANT ABSTRACT.doc" and send it to me electronically as a Word Perfect or Word file. Your abstract will be posted at <http://es.epa.gov/ncer/grants/>.

*NOTE:* Please pay special attention to the "Expected Results" section. The Government Performance and Results Act (GPRA) requires all EPA programs, including grants, to show results that ultimately improve responsible parties' ability to protect the environment and public health. A clear, concise description of how this research will accomplish this will help EPA explain why this project should be funded. *When discussing results and benefits to potential clients, note that the funding mechanism for all awards issued under STAR solicitations consist of assistance agreements from EPA; therefore, the primary purpose of a grant is to accomplish a public purpose of support or stimulation authorized by federal statute, rather than acquisition for the direct benefit or use of the Agency.* However, the EPA will monitor research progress through annual reports provided by grantees and other contacts, including site visits, with the Principal Investigator.

### Interaction(s) Between ORD Researchers and EPA Grant and Cooperative Agreement Applicants/Recipients

*In issuing a grant agreement, EPA anticipates that there will be no substantial EPA involvement in the design, implementation, or conduct of the research.* EPA/ORD does, however, encourage scientific interaction between its researchers and individuals conducting research funded under the auspices of the National Center for Environmental Research (NCER) Science To Achieve Results (STAR) program and other grant programs, ORD laboratories/Centers/Offices (L/C/O), other offices of EPA, and non-EPA organizations, and grant Principal Investigators after the award of an EPA grant for the sole purpose of exchanging information in research areas of common interest that may add value to their respective research activities. This interaction must be incidental to achieving the goals of the research under a grant. Interaction that is incidental does not involve resource commitments. Such interactions promote better science and enhance the integration of intramural and extramural research activities. However, these interactions must be in compliance with existing statutes, regulations, and policies of the Federal Government. See attached for guidance.

### QA Plan:

In addition to the Quality Assurance Statement provided in your proposal, we may also need more detailed quality assurance (QA) documentation in accordance with EPA's Quality System policy (see <http://epa.gov/quality/exmural.html> for more information). Generally, more detail will be needed if your project involves the collection or use of environmental data (including the use of data compiled from other sources such as databases or the literature), environmental monitoring, or the collection or use of data supporting the design, testing, and operation of environmental technology. In this case, a special term and condition may be added to the grant at the time of award detailing this additional QA documentation. Typically, this documentation is submitted to EPA with 90 days of award of the grant.

For STAR grants, the following forms of QA documentation may be required:



- Quality Assurance Statement (QAS): EPA may request that you provide additional details in your Quality Assurance Statement.
- Quality Management Project Plan (QMPP): EPA may request that you develop a QMPP in accordance with QA/G-1STAR (<http://es.epa.gov/ncer/guidance/g1starqadfinal.pdf>). A QMPP is a document that includes elements of the QA Statement but contains more information and details about the planned QA and QC activities. It is a combination of the Quality Management Plan and QA Project Plan described below.
- Quality Management Plan (QMP): In a few cases (for example, for Research Centers), EPA may request that you develop a QMP. A QMP documents how an organization plans, implements, and assesses the effectiveness of its quality assurance and quality control operations, in particular, how an organization structures its quality system, the quality policies and procedures, areas of application, and roles, responsibilities, and authorities. For more information on QMPs, see <http://epa.gov/quality/qmps.html>.
- Quality Assurance (QA) Project Plan: In some rare cases, EPA may request that you develop a QA Project Plan. A QA Project Plan is a document that describes the planning, implementation, and assessment procedures for a particular project, as well as any specific QA and QC activities. For more information on QA Project Plans, see <http://epa.gov/quality/qapps.html>.

The QA documentation identified in the Terms and Conditions of the final award package may be submitted electronically and should contain the signature of your QA Officer along with his/her contact information.

#### Budget:

If I have asked that you revise your budget, please send a **revised copy of the budget(s) - total and subs** - along with a justification sheet reflecting any changes. Also, please complete a new Form 424 (attached) to reflect new budget totals and any changes we have discussed. If you did not need to revise your budget but a yearly break down was not included as part of your proposal, **please send information on the total budget as well as separate itemized budgets for each year**. Note: I will need the original Form 424 with original signatures so please FedEx this form.

#### Foreign Travel:

EPA's Office of International Affairs must approve any foreign travel related to the grant well in advance of the travel date. To obtain this approval, I will need for you to submit a justification for the trip that includes the purpose, estimated budget, travel destination, agenda (if possible), abstract (if you presenting a paper), cost estimate, and the Fly America justification; (for example, for all foreign travel the recipient must comply with the Fly America Act. All travel must be on U.S. air carriers certificated under 49 U.S.C. Section 1371, to the extent that service by such carriers is available even if foreign air carrier costs are less than the American air carrier).

#### Miscellaneous Forms:

The "Certification Regarding Lobbying" and "Assurances - Non-Construction" Forms need to be completed and FedEx'ed to me (with the original signatures). These forms are attached in MS Word format or available on our website at <http://es.epa.gov/ncer/rfa/forms/>.

#### Human Subjects:

It will be necessary to determine if the work being performed under this grant award:

- o Involves Human Subjects (as defined by 40 CFR 26 Section 102(f))
- o Is considered research (as defined by 40 CFR Section 102(d))
- o Does involve Human Subjects, is deemed research, yet under the common rule

but maybe exempt. Please provide documentation and/or evidence of, though not necessarily by the IRB, this decision of exemption. It will be necessary for EPA to also agree that the work is exempt.

- o Does involve Human Subjects, is research and is not exempt, then no human subjects may be involved in this project(s), *including recruitment*, until it has been reviewed and approved by EPA's Human Subjects Research Review Official (HSRRO).

Please submit the following documents (if applicable):

Proof of the Institution's Human Subjects Institutional Review Board (IRB) - Federal Wide Assurance Number/FWA #.

A copy of the IRB approved protocol and copy of your Institutional Review Board (IRB) approval for the study described in the proposal.

A copy(ies) of the IRB approved Informed Consent Form(s) that you intend to use during the study and/or questionnaires. Approval must be made by the IRB of the Institution that proposes to conduct the work. Written evidence of any approvals made by the IRB in accordance with the Common Rule and copies of all documents used by the Institution's IRB for review and approval; including, protocol, detailed discussions of the proposed research, and written evidence of the IRB approved informed consent.

Grants Administration's approval of dollars:

No work can start or resources spent involving Human Subjects (*note that human subjects includes recruitment*), unless there is approval by the Institution's IRB and the EPA's Human Subjects Research Review Official (HSRRO); OR under certain circumstances, EPA can issue a conditional approval pending final determination as per 40 CFR 26.118.

*It is also important to note that although not specifically required by EPA, once the grant is underway, the PI submit to the EPA Project Officer annually, written evidence that the IRB has reviewed and approved the ongoing research.*

#### Animal Subjects:

The Recipient agrees to comply with the Animal Welfare Act of 1966 (P.L. 89-544), as amended, 7 USC 2131-2156. Recipient also agrees to abide by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training." (Federal Register 50(97): 20864-20865. May 20, 1985). The nine principles can be viewed at: <http://www.nal.usda.gov/awic/pubs/IACUC/vert.htm>. For additional information about the Principles, the recipient should consult the Guide for Care and Use of Laboratory Animals, prepared by the Institute of Laboratory Animal Resources, National Research Council and can be accessed at: <http://www.nap.edu/readingroom/books/labrats/>.



### Reporting Requirements:

Upon receipt of your grant award, you will need to send annual reports within 90 days of the anniversary of your start date. (If you request a no-cost extension, an annual report for the year of your extension will be required). A more extensive final report is due within 90 days of the end of your project period. Guidance on these reports are contained the attached files; please save these files for future reference. More information on these reports will be provided, but it is important to be aware of this requirement before a final funding decision is made.

After you have received official funding, the work must be attributed as sponsored (or co-sponsored as applicable) by the STAR program in writings or discussions about your EPA Science to Achieve Results (STAR) research. EPA's full or partial support must be acknowledged in journal articles, oral or poster presentations, news releases, interviews with reporters and other communications. Any documents developed under the agreement for distribution to the public or inclusion in a scientific, technical, or other journal shall include the following statement: This publication [article] was developed under a STAR Research Assistance Agreement No. \_\_\_\_\_ awarded by the U.S. Environmental Protection Agency. It has not been formally reviewed by the EPA. The views expressed in this document are solely those of [name of recipient] and the EPA does not endorse any products or commercial services mentioned in this publication. A graphic that can be converted to a slide or used in other ways, such as on a poster, is located at [http://es.epa.gov/ncer/guidance/star\\_images.html](http://es.epa.gov/ncer/guidance/star_images.html). EPA expects recipients to use this graphic in oral and poster presentations.

It is also important to the STAR program that you provide us with a list of any major awards that you receive for your research during your tenure as a STAR grantee. Examples of awards include best paper, best author, or any award of national or international significance. Acknowledging the significant awards to our grantees often helps us demonstrate the quality of our program to the many audiences that review our research results. In the future, we may ask you to tell us about any research results conducted under STAR that are particularly noteworthy as well.

I am looking forward to hearing from you soon. As mentioned above, most information should be sent as e-mail attachments but the final hard copies with original signatures will need to be Fed Ex'ed to me at the address below. If you have any questions regarding this memo or the STAR Program, please do not hesitate to contact me.

Kind Regards,

Nigel Fields  
Environmental Health Scientist  
US EPA, National Center for Environmental Research  
Washington DC  
202.343.9767  
[fields.nigel@epa.gov](mailto:fields.nigel@epa.gov)

FEDEX/ Courier Address only:

Nigel Fields  
US EPA, Woodies Building  
1025 F Street, NW (Rm 3107-C)  
Washington, DC 20004



**9 August 2006**

**TO:** Nigel Fields, US EPA Project Officer

**FROM:** Marie Lynn Miranda, Associate Research Professor, Duke University  
and Director, Children's Environmental Health Initiative

**SUBJECT:** **Re: Potential STAR Center grant —Southern Center on  
Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO)**

Dear Dr. Fields,

We are very excited about the opportunity to move forward with our important research agenda as laid out in our Children's Environmental Health Center proposal, the Southern Center on Environmentally-Driven Disparities in Birth Outcomes. Below, I provide a point-by-point response to the questions raised in your letter dated August 6, 2006. We have completed all requested forms as outlined in your letter, either sent via email or Fed-ex, as appropriate. Please let us know if there are any additional items you require, and we will transmit these to you immediately.

**Your questions** regarding the following situations associated with this grant award:

- 1) Any changes to your proposal, i.e., are personnel moving to other universities and such?  
*No.*
- 2) Any foreign travel?  
*No.*
- 3) Any federal employees on your grant?  
*No.*
- 4) Conducting workshops?  
*No.*
- 5) Human and/or animal subjects?  
*Yes, and the requested information is attached.*
- 6) Development of questionnaires/and or surveys?  
*No.*

**Grants Administration Division Number:**

We have submitted with this letter the sf424 and the sf424b forms, as well as the key contacts sheet, and await our GAD number. Once assigned, we will use this number on any correspondence, forms, and reports sent to you or anyone else at EPA, as well as in the acknowledgements section of presentations, posters, and papers.

**Abstract:**

We have attached our abstract in the NCER STAR grant abstract format.

**Interaction(s) Between ORD Researchers and EPA Grant and Cooperative Agreement Applicants/Recipients**

We look forward to working with the EPA, its researchers, and individuals in an appropriate manner to exchange ideas and advance our research.

**QA Plan:**

We will not be collecting environmental data, conducting environmental monitoring, or testing environmental technology. Please inform us if you need further Quality Assurance information or documentation.

**Budget:**

Our budget has not been revised. The completed sf424 and sf424b are attached and have been sent via Fed-ex with the appropriate signatures.

**Foreign Travel:**

SCEDDBO's research does not involve any foreign travel.

**Miscellaneous Forms:**

The "Certification Regarding Lobbying" and "Assurances – Non-Construction" forms have been completed and signed by the appropriate individuals, and are enclosed in the Fed-ex package.

**Human Subjects:**

SCEDDBO's research projects A: "Mapping Disparities in Birth Outcomes" and B: Healthy Pregnancy, Healthy Baby: Studying Racial Disparities in Birth Outcomes" involve Human Subjects (as defined by 40 CFR 26 Section 102(f)), are considered research (as defined by 40 CFR Section 102(d)), and are not exempt. We have received IRB approval for both of these projects. For Research Project A, the Duke University IRB approved protocol number is 1081. For Research Project B, the IRB approved protocol number is 7227-06-5R1ER.

Your letter states that "no human subjects may be involved in this project(s), *including recruitment, until* it has been reviewed and approved by EPA's Human Subjects Research Review Official (HSRRO)." We would like to clarify that Research Project B of this study builds upon a pre-existing, fully operational pilot study, approved by Duke's Institutional Review Board, which provided the data for the proposal. We would like to transition from



pilot to full-fledged study without interruption in recruitment. Stopping recruitment, even for a short time, will reverse important momentum. Thus, depending on the time required to attain approval from the HSRRO, we would request conditional approval pending final determination per 40 CFR 26.118.

Duke University's Federal Wide Assurance Number is 00000265 for human subjects in non-medical research (Research Project A) and M1106 for human subjects in medical research (Research Project B). We have included the required IRB approvals and IRB approved Informed Consent Forms.

**Animal Subjects:**

Research Project C: "Perinatal Environmental Exposure Disparity and Neonatal Respiratory Health" involves IACUC approved research with animal subjects. The Duke University IACUC approved Protocol Registry Number is A329-05-11. Duke University's IACUC assurance of compliance number is A3195-01. The associated IACUC approval is attached.

**Reporting Requirements:**

Upon receipt of our grant award, we will send annual reports within 90 days of the anniversary of the start date. We will also send a more extensive final report within 90 days of the end of the project period.

After we have received official funding, we will attribute our work as sponsored or co-sponsored by the STAR program in writings and discussions about our EPA Science to Achieve Results research.

We will inform you of any major awards that we receive for our research during our tenure as a STAR grantee.

We very much look forward to working with you and advancing SCEDDBO's ambitious research agenda. With these commitments, we can ultimately improve the environmental health of our nation's children.

With all best regards,

(b) (6)

Marie Lynn Miranda, Ph.D.  
SCEDDBO Principal Investigator

**Tanya  
Lawrence/DC/USEPA/US**

01/09/2007 10:35 AM

**To** William Stelz/DC/USEPA/US@EPA  
Nigel Fields/DC/USEPA/US@EPA, Roberto  
**cc** Perez/DC/USEPA/US@EPA, Patrick  
Chang/DC/USEPA/US@EPA  
**bcc**

**Subject** Re: Research Proposal for Children's Center - Duke  
University

Bill,

Thanks for the opportunity to review this proposal. The decision to explore the interaction of environmental and other stressors on the higher rates of poor birth outcomes among African-American and Hispanic women, including Hispanic women born outside of this country, would not be a race-based decision subject to the Supreme Court's Adarand ruling. The decisions to conduct and support this research would be based on an interest in addressing the health disparities, which is a race-neutral criterion.

Please let me know if you have additional questions or concerns.

Tanya Lawrence  
Office of General Counsel  
Civil Rights and Finance Law Office (2399A)  
202-564-2916

**William  
Stelz/DC/USEPA/US**

01/04/2007 03:37 PM

**To** Tanya Lawrence/DC/USEPA/US@EPA  
**cc** Roberto Perez/DC/USEPA/US@EPA, Nigel  
Fields/DC/USEPA/US@EPA  
**Subje** Research Proposal for Children's Center - Duke  
**ct** University

Tanya:

Hi

Roberto Perez asked that I forward the following proposal for your comment/review. NCER has historically provided OGC's OCLO office with copies of RFAs and or research proposals, when applicable, in order to ensure that proposed research/language does not cause possible Adarand problems. I know that this proposal is long but if you could look at the language in and around page 124 of the attached proposal to see if this may raise any issues? We want to verify that this language is OK. If you have any questions, please feel free to contact any one of us. If by chance you have looked at this and already responded, please verify.

thanks for your help

Bill

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Duke\_Miranda Proposal.pdf

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William G. Stelz, CPG  
Acting Chief of Staff  
USEPA/ORD/NCER/8723F  
Phone: 202-343-9802  
Fax: 202-233-0677  
1200 Pennsylvania Ave NW (8723F)  
Washington DC 20460-0001

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For FedEx use:  
Actual Office ( in person ) Location:  
Woodies Building  
Room 3106  
1025 F Street NW  
Washington DC 20004

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# Memo

**To:** Nigel Fields  
**From:** Marie Lynn Miranda  
**CC:** Trish McMillan  
**Date:** January 25, 2007  
**Re:** Response to your email dated 1-19-2007

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Below, please find our responses to the ten questions regarding our children's center application that you raised in a recent email. Your questions are reproduced in italics, and our responses follow.

(b) (4)

Across the multiple components of the Southern Center for Environmentally Driven Disparities in Birth Outcomes, Marie Lynn Miranda (PI) has an overall commitment of (b) (6) effort, which is well within the expectation set for center directors.

(b) (4)

*Interactions with applicants/grantees may occur at two levels: consultation and cooperation, descriptors which describe and discriminate between the degree of involvement of an ORD researcher with an extramural grantee or cooperative agreement applicant/recipient:*

- *Consultation occurs when an ORD researcher discusses with an applicant/grantee the scientific aspects of the research under the application or grant. This is an intellectual exchange that conveys no commitment on the part of the ORD researcher to directly participate in the applicant's/grantee's research. An ORD researcher may also collect data or samples at the same time, site, or location where a grantee is conducting research; although the ORD researcher and the grantee may consult about their individual activities, these research activities and the ORD researcher's consultation is incidental to achieving the basic goals of the grantee's project.*
- *Cooperation involves the sharing or comparing of samples, equipment, facilities, data, and/or models during the conduct of the research in which the interaction is substantial and would require the award of a cooperative agreement rather than a grant. Substantial involvement occurs when the collaboration or cooperation of the ORD researcher is*

*necessary to achieving the overall goals of the research supported by a cooperative agreement.*

*In either case, the recipient should be reminded of the level of interaction permitted under our assistance agreements.*

At Duke University, we have typically referred to our interactions with research at US Government facilities and with colleagues in Government service, as *collaborations*. To clarify our research plan, we anticipate a *consultative* rather than *cooperative* arrangement with EPA researchers. We will interact with Dr. M. Ian Gilmour, of the Department of Experimental Toxicology at USEPA, Research Triangle Park, NC, strictly as a consultant. We have fully evaluated the feasibility of performing the necessary components of the research plan and single and dual exposure challenges with ozone, and airborne particulate at Duke. Beginning July 1, 2006, we have had success in implementing aerosolization techniques for generating ultra-fine and fine sized particulate "clouds" for *in vivo* exposures of our animal models. We have successfully achieved deposition of surrogate radio-labeled ultra-fine and fine sized particles in adult mice, and are presently adjusting the aerosol generation/exposure system to be able to accommodate 3-4 day old pups. We are now confident that we can proceed with our initial gas and particulate exposures here at Duke without having to rely on outside laboratory support. We are fully confident we can achieve our stated goals completely at Duke's Animal Inhalation facility and within the time frame proposed. This approach greatly facilitates research design and implementation.

3. *The recipient makes mention of "participating in regional, state and federal policy dialogues to provide decision makers with policy-relevant science-based information... and facilitating bi-directional exchanges between Center investigators, community members, publish health advocacy groups, and policy makers..." References to advocacy and the legislative process are made in the outreach core. Here's the lobbying language from OMB Circular A-21: Reference is made to the common rule published at 55 FR 6736 (2/26/90), and OMB's government-wide guidance, amendments to OMB's government-wide guidance, and OMB's clarification notices published at 54 FR 52306 (12/20/89), 61 FR 1412 (1/19/96), 55 FR 24540 (6/15/90) and 57 FR 1772 (1/15/92), respectively. In addition, the following restrictions shall apply:*

*Notwithstanding other provisions of this Circular, costs associated with the following activities are unallowable: (1) Attempts to influence the outcomes of any Federal, State, or local election, referendum, initiative, or similar procedure, through in kind or cash contributions, endorsements, publicity, or similar activity; (2) Establishing, administering, contributing to, or paying the expenses of a political party, campaign, political action committee, or other organization established for the purpose of influencing the outcomes of elections;*

*(3) Any attempt to influence –*

*(i) the introduction of Federal or State legislation;*

*(ii) the enactment or modification of any pending Federal or State legislation through communication with any member or employee of the Congress or State legislature, including efforts to influence State or local officials to engage in similar lobbying activity; or*

*(iii) any government official or employee in connection with a decision to sign or veto enrolled legislation;*

*(4) Any attempt to influence –*

*(i) the introduction of Federal or State legislation; or*

*(ii) the enactment or modification of any pending Federal or State legislation by preparing, distributing, or using publicity or propaganda, or by urging members of the general public, or any segment thereof, to contribute to or participate in any mass demonstration, march, rally, fund raising drive, lobbying campaign or letter writing or*



telephone campaign; or (5) Legislative liaison activities, including attendance at legislative sessions or committee hearings, gathering information regarding legislation, and analyzing the effect of legislation, when such activities are carried on in support of or in knowing preparation for an effort to engage in unallowable lobbying.

The following activities are excepted from the coverage of subsection a: (1) Technical and factual presentations on topics directly related to the performance of a grant, contract, or other agreement (through hearing testimony, statements, or letters to the Congress or a State legislature, or subdivision, member, or cognizant staff member thereof), in response to a documented request (including a Congressional Record notice requesting testimony or statements for the record at a regularly scheduled hearing) made by the recipient member, legislative body or subdivision, or a cognizant staff member thereof, provided such information is readily obtainable and can be readily put in deliverable form, and further provided that costs under this section for travel, lodging or meals are unallowable unless incurred to offer testimony at a regularly scheduled Congressional hearing pursuant to a written request for such presentation made by the Chairman or Ranking Minority Member of the Committee or Subcommittee conducting such hearings; (2) Any lobbying made unallowable by subsection a.(3) to influence State legislation in order to directly reduce the cost, or to avoid material impairment of the institution's authority to perform the grant, contract, or other agreement; or (3) Any activity specifically authorized by statute to be undertaken with funds from the grant, contract, or other agreement.

The recipient must be made aware of the restrictions on lobbying. **THIS IS VERY IMPORTANT.** The COTC project should be updated to ensure that what's proposed is compliant with the above language.

The work proposed to be undertaken under the SCEDDBO COTC falls within exception #1. Our COTC activities fall into five categories:

- **Neighborhood assessment:** The COTC will support the activities of Research Project B by serving as the direct liaison to the community for the neighborhood assessment component of the research project.
- **Nursing program participants:** The COTC will work with nursing schools throughout the Triangle area to incorporate concepts of environmental health into nursing curricula.
- **Culturally-appropriate advisory materials on environmental contaminants:** The COTC will work to take existing and well-accepted scientific information on environmental contaminants and transform it into a format that is more culturally appropriate. For example, information on fish consumption advisories might be developed in a photo-novella, Spanish language format for the immigrant Hispanic community in North Carolina.
- **Training for local health department personnel:** Leveraging resources available through the GISSA Core, the COTC will work in partnership with local health departments to develop their capacity to use spatially referenced data architecture to improve the delivery of environmental health services.
- **Policy dialogues:** The COTC will serve as a *technical backstopper* to local, regional, state, and national policymakers as requested by these policymakers. By this, we mean we will compile relevant scientific knowledge and available data relevant to an issue under consideration. The COTC will NOT be involved in making policy recommendations of any kind. The COTC will provide a venue for bringing together the multiple stakeholders on a particular policy question to facilitate dialogue among them.

None of these activities fit into the category of unallowable costs and all are consistent with the allowable "technical and factual presentations."



4. *The out-years of funding were not itemized. I'm not sure how this has been handled in the past. We tend to get an itemized budget with accompanying budget justifications for all years of funding. The last center packages I reviewed were the PM Centers and they were itemized for all 5 years of funding.*

Please see attached Excel spreadsheet that provides component-by-component and year-by-year detail on the SCEDDBO budget. Also see the attached compendium MSWord document that provides a component-by-component and year-by-year budget justification.

5. *Page 166 makes reference to a "welcome bay gift". Although the gift is for a relatively small amount, it is still an unallowable cost. The budget justification needs to be revised to remove that charge.*

This line item was for participant incentives, and the language of the budget justification has been adjusted to reflect this clarification.

6. *On page 166 as well, I don't know how much funds are being used to fund the research tech II.*

See the documents referenced in #4 above.

7. *Page 263. Supplies need to be itemized. All of the other budget justifications for supplies have included a description of what the funds will be used for.*

See the budget justification document referenced in #4 above.

8. *Page 264 makes reference to equipment. You nor the recipient included equipment in the budget. Equipment is defined as tangible, nonexpendable personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. If one of the items (computer workstations, etc.) have a value of \$5,000 or greater, then they need to be listed as equipment. If that is the case, you'll need to change the cost review as well as E.8.*

None of the proposed minor equipment has a per unit acquisition cost that exceeds \$5000. The language of the budget justification has been adjusted to reflect this clarification.

9. *The consultant charges should be included in the contractual line in your budget. I assume the charges are within our cap of \$557.28 per day and \$69.66 per hour.*

Consultant costs are included in contractual line of the Administrative Core budget and are within the specified cap.

10. *Because of the numerous handwritten changes and the questions I've raised above, I would like to see a clean set of budgets submitted by Duke.*

Please see the documents referenced in #4 above.

mmiranda  
<mmiranda@duke.edu>  
03/06/2007 12:24 PM

To Nigel Fields/DC/USEPA/US@EPA  
cc trish.mcmillan@duke.edu  
bcc

Subject Re: The final five.

Nigel,

Thanks for this update. Please see my responses below.

mlm

Fields.Nigel@epamail.epa.gov wrote:

As a follow-up to our telephone conversations a couple of weeks ago regarding the internal review of your proposal, here are the remaining five outstanding concerns for moving your proposal forward. Only four require a response from you.

1. To address potential overlapping scientific and budgetary concerns, please briefly explain how Project 2 of SCEDDBO differs from the project goals of the Center for Geospatial Medicine. Where does CGM end and SCEDDBO begin? Does it comes to completion this summer?

The primary purpose of the CGM is to develop new statistical and mathematical methods for disentangling the etiology of complex human disease. The methods are applicable to any complex disease endpoint, but we started with pregnancy outcomes as our prototype health endpoint. In many ways, the CGM work shaped and continues to shape our ideas for how to organize a children's environmental health center. The CGM did cover a portion of the costs associated with the pilot study that provided the pilot data for Project 2 in our children's center application. The vast majority of the funding for the pilot study, however, came from the Office of the Provost, the Department of Obstetrics, and the Dean's Office here at the Nicholas School of the Environment. The non-renewable end-date on the CGM grant is 7-31-2007.

2. No action required here, but a reminder from the internal reviewer regarding communication with policymakers: **The recipient should be reminded that under exception #1, the technical and factual presentations must be made *in response to documented request*. And obviously, EPA financial assistance may not be used to conduct research for direct use by EPA to develop federal policies, guidelines, guidance, or regulations.**

Duly noted.



3. Please send a brief statement clarifying the nature of the "community assessments," assuring that they are not a part of the state's program and will not collect access to care data.

In the COTC portion of our grant proposal, we make reference to "community-based neighborhood assessments." These neighborhood assessments are focused on building a spatial database of the built environment in Durham. The built environment data will then be linked to the health data in Projects 1 and 2. These are assessments of the *physical environment*. We will not assess people at all. It is not part of any state program, and we do not have any plans to collect access to care data. They are "community-based" because we plan to solicit partners from the community to help us in the data collection stages.

4. The reviewer and general counsel attorney are concerned about the hotline. Please let me know (a) how much of the hotline will be funded by the CEHI and/or SCEDDBO and (b) how referrals will be handled. Please confirm that (a) the EPA-funded COTC hotline reps will not disseminate general medical advice, and (b) referrals will not be made to particular doctors or specialists. Here's the reviewer's latest statement:

**\*I hope we can put the hotline issue to bed. Initially you [meaning me, Nigel] indicated that EPA would not be paying for the hotline. From page 108 below, it looks like we are. The COTC will help staff the toll-free number and advertise it to community residents as a mechanism for accessing information about children's environmental health, as well as the resources of the SCEDDBO and Duke more generally. People staffing the line will be English-Spanish bilingual. If we are paying for the dissemination of environmental exposure information like with the referrals above, then we are OK. Just want to verify this since initially you told me that the grant would not be paying for it**

CEHI has maintained a toll-free number for several years. As a policy, we do not disseminate general medical advice, nor do we make referrals to particular doctors or specialists as clinicians. We have no intention of changing this policy. We tend to get questions like, "How can I reduce the allergens and asthma triggers in my home?" In response to a question like this, CEHI staff typically provide an overview response and then send federal brochures on the topic. Alternatively, we may get a question like, "Where can I get my child tested for lead?" (answer: your county health department) or "Where can I get my water tested for inorganics?" (answer: connect them with the state office or local water treatment office that handles these requests). Just as we do not make referrals to particular doctors or specialists, we do not make referrals to particular environmental remediation or environmental testing firms. We do sometimes get requests along the lines of: "Who at Duke is working on such-and-such environmental issue?" If the callers have email access, we typically refer them to the relevant faculty websites. If they do not have email access, we provide telephone contact numbers. Sometimes, the faculty to whom we refer callers are in fact medical doctors who see patients in clinic, but we are not referring the callers to the faculty for the purposes of clinical care.

If it would simplify matters, I am happy to cover the costs associated with the toll-free line from other (non-EPA) funds.



5. Please forward a copy (email or fedex) of the IRB approved questionnaire used in the CGM pilot study.

I am out of the office today. I will send them as soon as I reach the office tomorrow.

Nigel A. Fields  
US Environmental Protection Agency  
National Center for Environmental Research  
Washington, DC 20460  
Phone calls preferred: 202.343.9767

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Marie Lynn Miranda, Ph.D.  
Director, Children's Environmental Health Initiative  
Nicholas School of the Environment and Earth Sciences  
Box 90328  
Durham, NC 27708  
919-613-8023  
919-684-3227 (fax)  
[mmiranda@duke.edu](mailto:mmiranda@duke.edu)  
[www.env.duke.edu/cehi](http://www.env.duke.edu/cehi)

---



> cohort?  
>  
> Trish  
>  
> --On Wednesday, April 04, 2007 8:18 AM -0400  
> Fields.Nigel@epamail.epa.gov  
> wrote:  
>  
>>  
>> Thank you, Trish.  
>>  
>> Why was this protocol given an electronic approval and the birth  
> cohort  
>> given a stamped approval? Is there a different process for human and  
>> non human reviews?  
>>  
>> -Nigel  
>>  
>  
>  
>  
> %%%  
> Trish McMillan, CRA  
> Business Manager  
> Children's Environmental Health Initiative  
> Nicholas School of the Environment & Earth Sciences  
> Duke University, Box 90328  
> Durham, NC 27708-0328  
> Phone: 919.613.8137  
> Fax: 919.684.3227  
> trish.mcmillan@duke.edu  
> www.env.duke.edu/cehi  
>  
>

%%  
Trish McMillan, CRA  
Business Manager  
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

OFFICE OF  
RESEARCH AND DEVELOPMENT

MEMORANDUM

DATE: April 10, 2007

SUBJECT: Request for Human Subjects Approval (R833293): Mapping Disparities in Birth Outcomes (Project A of Duke University Children's Center)

FROM: Nigel A. Fields  
National Center for Environmental Research (8723F)

THRU: Becki M. Clark, Director (b) (6)  
Environmental Sciences Research Division (8723F)

TO: Roger Cortesi  
National Center for Environmental Research (8701F)

This memorandum requests approval under Section 120 of 40 CFR 26 for the study entitled, *Mapping Disparities in Birth Outcomes*. This project is one of three proposed research studies of the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (R833293). This project will collect private identifiable information and thus involves human subjects as defined by 40 CFR 26 Section 102 (f) and considered research as defined by 40 CFR 26 Section 102 (d), thus is not exempt. The aforementioned proposed Center expands upon the original pilot Center entitled "Duke Center for Geospatial Medicine" as recorded in the IRB application.

The approval notice and materials submitted to Duke University are attached.

Federalwide Assurance No: 00000265  
EPA Grant Number: R833293  
Center Title: Southern Center on Environmentally-Driven Disparities in Birth Outcomes  
Project Title: *Mapping Disparities in Birth Outcomes*  
Institution: Duke University  
Project Investigator: Marie Lynn Miranda, Ph.D.

Attachments:

- a) Duke University Non-Medical Research IRB Approval
- b) Request for Secondary Analysis of Existing Data application and protocol
- c) Project A proposal from Center application



NICHOLAS SCHOOL OF THE ENVIRONMENT AND EARTH SCIENCES  
DUKE UNIVERSITY

CHILDREN'S ENVIRONMENTAL HEALTH INITIATIVE  
Marie Lynn Miranda, PhD • Director

5 September 2007

Nigel A. Fields  
Environmental Research Program Manager  
National Center for Environmental Research  
USEPA Headquarters  
Ariel Ros Building  
1200 Pennsylvania Avenue, N.W.  
**Mail Code:** 8723F  
Washington, DC 20460

Dear Nigel:

As the activities of the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO) have started to fully settle following final funding decisions and we have staffed our various projects, it has become evident that SCEDDBO will benefit from moving Martha Keating into the position of Principal Investigator for the Community Outreach and Training Core (COTC). Ms. Keating will replace Joshua Tootoo as PI.

Ms. Keating participated significantly in writing the COTC proposal and is a natural fit for this leadership role. Ms. Keating is an environmental scientist specializing in public health and air pollution. She is a graduate of the University of New Hampshire and the School of Public Health at the University of North Carolina at Chapel Hill. Ms. Keating is currently an Associate in Research at the Children's Environmental Health Initiative in the Nicholas School of the Environment and Earth Sciences at Duke University. Prior to joining Duke in October 2006, Ms. Keating was Executive Director of Keating Environmental, a consulting firm whose clients included national, regional, and state environmental groups. Her work has focused on power plant environmental impact issues, including mercury and other air toxics, and power plant combustion waste.

From 1988 to 1998, Ms. Keating was a staff scientist at the U.S. Environmental Protection Agency. She served as project manager for numerous projects dealing with hazardous air pollutants and regulatory authorities of the Clean Air Act. Ms. Keating has broad experience with State and local air toxics control programs, particularly with respect to mercury policy, emissions, controls, and exposure. She was the project director and a principal author of the EPA's Mercury Study Report to Congress, for which she was awarded the EPA's Bronze and Silver Medals, and the Assistant Administrator for Air and Radiation Risk-Takers Award. She

also earned Bronze Medals for implementing a course in risk communication and for developing the high-risk list of pollutants for the EPA's Early Emissions Reduction Rule.

Ms. Keating's leadership in the position of PI for COTC will be a tremendous asset for SCEDDBO. Please let me know whether you are agreeable to this change.

With all best regards,

(b) (6)

Marie Lynn Miranda, Ph.D.  
Principal Investigator, SCEDDBO

(b) (6)

Maria Scripa  
Assistant Director, Office of Research Support





NICHOLAS SCHOOL OF THE ENVIRONMENT AND EARTH SCIENCES  
DUKE UNIVERSITY

CHILDREN'S ENVIRONMENTAL HEALTH INITIATIVE  
Marie Lynn Miranda, PhD • Director

5 September 2007

Nigel A. Fields  
Environmental Research Program Manager  
National Center for Environmental Research  
USEPA Headquarters  
Ariel Ros Building  
1200 Pennsylvania Avenue, N.W.  
**Mail Code:** 8723F  
Washington, DC 20460

Dear Nigel:

As we move forward in implementing the plans for the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO), it is critical for us to establish a well-balanced and expert Science Advisory Committee (SAC). Thus we would like to invite six individuals to join our SAC:

1. **Ian Gilmour, Ph.D.**, is the Lead Research Biologist in the Experimental Toxicology Division at the U.S. Environmental Protection Agency. Dr. Gilmour is the team leader of the inhalation exposure facility supervising twelve inhalation engineers and a core chemistry facility. He is an expert in animal models and has performed extensive research on air pollution, environmental toxicology, and inhalation.
2. **Jay S. Kaufman, Ph.D.**, is a social epidemiologist at the University of North Carolina at Chapel Hill. Dr. Kaufman studies the ways in which health status varies by race, class and other socioeconomic variables. His current focus is on analytic methodology and on reproductive outcomes, cardiovascular disease, and provision of health care in the United States. Current projects include research on: social and community factors in the etiology of preterm birth; nonparametric methods for covariate control and identification of direct effects for social factors; and racial/ethnic disparities associated with differential provision of medical care.
3. **Philip J. Landrigan, M.D., M.Sc.**, is the Director of the Center for Children's Health and the Environment at the Mt. Sinai School of Medicine. He is the Ethel H. Wise Professor and Chair of the Department of Community and Preventive Medicine. He is also the Director of Environmental and Occupational Medicine. Dr. Landrigan served as a commissioned officer in the United States Public Health Service from 1970 to 1985.

Dr. Landrigan also served as Senior Advisor on Children's Health to the Administrator of the U.S. Environmental Protection Agency. While at the EPA, he was responsible for establishing a new Office of Children's Health Protection.

4. **Brian Letourneau** is the Director of the Durham County Health Department. The mission of the Durham County Health Department is to preserve, protect and enhance the general health and environment of the community. Mr. Letourneau has been an integral force in working toward that mission. His interests include the impact of the physical and built environment on health outcomes in low income and minority populations in the county.
5. **Jason Moore, Ph.D.**, is a prominent geneticist at Dartmouth. The primary focus of his research program is to develop, evaluate, and apply novel computational and statistical algorithms for identifying combinations of DNA sequence variations along with combinations of environmental factors that are predictive of common disease endpoints. His group has developed the first new methodology and open-source software package designed for detecting and characterizing gene-gene and gene-environment interactions. This open-source multifactor dimensionality reduction (MDR) software has been downloaded more than 7500 times since 2005. The goal of his research is to continue to develop, evaluate, and apply new and novel approaches for identifying genes and continue the interpretation of nonlinear interaction models. Dr. Moore's research program lies at the intersection of genetics, genomics, biostatistics, epidemiology, and computer science.
6. **Louise Ryan, Ph.D.**, is the Henry Pickering Walcott Professor of Biostatistics at Harvard University. Dr. Ryan works on statistical methods related to environmental risk assessment for cancer, developmental and reproductive toxicity, and other non-cancer endpoints such as respiratory disease. She also works on epidemiological methods for the study of birth defects and adverse reproductive outcomes. Her recent endeavors include community based environmental health research and assessing air quality in Boston. Dr. Ryan is a fellow of the American Statistical Association and in the International Statistics Institute.

These proposed members were selected for pertinent expertise and diversified specializations. They each share our goal of improving children's environmental health and will provide us with valuable advice and guidance.

Please let me know whether you are agreeable to this configuration of our Science Advisory Committee. If your response is favorable, I will move forward on inviting these scientists to join our SAC.

With all best regards,

(b) (6)

Marie Lynn Miranda, Ph.D.  
Principal Investigator, SCEDDBO

(b) (6)

Marina Sripa  
Assistant Director  
Office of Research Support





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH  
WASHINGTON, DC 20460

10 September 2007

OFFICE OF  
RESEARCH AND DEVELOPMENT

Marie Lynn Miranda, Ph.D.  
Children's Environmental Health Initiative, Director  
Nicholas School of the Environment and Earth Sciences  
Duke University  
P.O. Box 90328  
Durham, NC 27708-0328

Dear Dr. Miranda, *Marie Lynn:*

I am pleased to express my agreement with the proposed Science Advisory Board members of the Southern Center on Environmentally-Driven Disparities in Birth Outcomes. The selected individuals bring strong locally, nationally and internationally-focused expertise useful for all of the SCEDDBO projects. Considering the range of scientific and statistical challenges SCEDDBO faces and the opportunities for broad translation of the findings, I believe this proposed committee will provide excellent guidance and insight over the next five years.

Best in All,

(b) (6)

Nigel A. Fields





NICHOLAS SCHOOL OF THE ENVIRONMENT AND EARTH SCIENCES  
DUKE UNIVERSITY

CHILDREN'S ENVIRONMENTAL HEALTH INITIATIVE  
Marie Lynn Miranda, PhD • Director

17 September 2007

Nigel A. Fields  
Environmental Research Program Manager  
National Center for Environmental Research  
USEPA Headquarters  
Ariel Ros Building  
1200 Pennsylvania Avenue, N.W.  
**Mail Code:** 8723F  
Washington, DC 20460

Reference: U.S. EPA Grant RD-83329301, Southern Center on Environmentally-Driven Disparities in Birth Outcomes

Dear Nigel:

As you are aware, the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO) experienced a great loss with the passing of Dr. Marcy Speer in August. Dr. Speer was integrally involved in SCEDDBO, as a Center Co-Director (5% effort) within the Administrative Core and an investigator on Project B (5% effort). We have carefully considered how best to restructure SCEDDBO and would like to request the following changes.

- **Administrative Core.** We would like to appoint Dr. Richard Auten to the position of Center Co-Director. Dr. Sherman James will continue as the other Center Co-Director. Dr. Auten is leading our animal model-based investigations, and it will benefit our Center to move him into a senior leadership position. This reorganization will move Dr. Speer's 5% effort within the Administrative Core to Dr. Auten. Dr. Auten's percent effort on **(b) (6)**
- **Project B.** We would like to direct the financial resources associated with Dr. Speer's 5% effort as an investigator on Project B toward increasing the effort we had previously allocated for a statistical analyst from the Center for Human Genetics. Dr. Allison Ashley-Koch, a genetic epidemiologist already associated with SCEDDBO, will supervise the analyst. Increasing this effort will allow us to move forward with our genetic analysis in a way that is consistent with Dr. Speer's planned contributions to Project B.

Losing Marcy was hard on all of us both personally and professionally. We are determined to advance the ambitious research agenda on environmentally-induced health disparities that she helped us to develop. We believe these proposed changes will allow us to move forward in a timely and scientifically meaningful way. Please let us know whether you are agreeable to these changes.

With all best regards,

(b) (6)

Marie Lynn Miranda, Ph.D.  
Principal Investigator, SCEDDBO

(b) (6)

Maria Scripa/  
Assistant Director, Office of Research Support



NICHOLAS SCHOOL OF THE ENVIRONMENT AND EARTH SCIENCES  
DUKE UNIVERSITY

CHILDREN'S ENVIRONMENTAL HEALTH INITIATIVE  
Marie Lynn Miranda, PhD • Director

19 September 2007

Nigel A. Fields  
Environmental Research Program Manager  
National Center for Environmental Research  
USEPA Headquarters  
Ariel Ros Building  
1200 Pennsylvania Avenue, N.W.  
**Mail Code:** 8723F  
Washington, DC 20460

Reference: U.S. EPA Grant RD-83329301, Southern Center on Environmentally-Driven Disparities in Birth Outcomes

Dear Nigel:

Our children's center supports a facility called the "Geographic Information System and Statistical Analysis" (GISSA) Core. Professor Jon Goodall serves as an investigator within that core. Dr. Goodall moved from Duke University to the University of South Carolina (USC) effective 1 July 2007. Our preference is for Dr. Goodall to continue his work through the GISSA Core, but to do so from USC. In particular, he participates in our monthly meetings via teleconference and is taking the lead on developing the spatial data layers on water quality.

The Civil and Environmental Engineering Department at USC has Environmental, Geotechnical, Hydraulic, Engineering Materials, and Structural research laboratories. All laboratories support computer automation and data acquisition. The College of Engineering and Information Technology offers excellent computer resources through networked and personal computers, as well as a supercomputer housed in the School of Engineering. Computer-aided drawing, graphics, word processing, statistics, and other software are also available. With these resources, Dr. Goodall is well-supported to undertake the work we have assigned to him within the overall goals of the Southern Center on Environmentally-Driven Disparities in Birth Outcomes.



Pg. 2

We request permission to issue a subcontract in the amount of (b) (6) for the current year for Dr. Goodall's salary and fringe to the University of South Carolina. Dr. Goodall's proposed five year budget, to be issued as yearly subcontracts from Duke, is attached. Dr. Goodall's continued participation in the GISSA Core will be a tremendous asset for SCEDDBO. Please let me know whether you are agreeable to this change.

With all best regards,

(b) (6)

Marie Lynn Miranda, Ph.D.  
Principal Investigator, SCEDDBO

(b) (6)

Mania Scripa  
Assistant Director, Office of Research Support

cc: Jon Goodall

Enclosure

Children's Environmental Health Center - GIS and Statistical Analysis

	Year 1	Year 2	Year 3	Year 4	Year 5
Personnel (percent effort)					
faculty support - M	(b) (6), (b) (4)				
faculty summer sup			(b) (4), (b) (6)		
faculty support - A					
faculty summer sup					
faculty support - A					
faculty support - Je					
faculty summer sup					
GIS analyst - TBN					
GIS analyst - TBN					
GIS analyst (from C					
statistics post-doc -					
statistics graduate s					
statistics graduate s					
statistics graduate s					
statistician III (0%,					
analyst programme					
Fringe	(b) (6), (b) (4)				
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GIS an					
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(b) (4), (b) (6)  
statistician III  
analyst program

**Contractual costs**  
Montserrat Fuentes

**Equipment**

**Supplies**

**Travel**

**Other**

computer usage fee  
lab access fee  
data acquisition  
hardware, software and upgrades  
server capacity

**Subtotal**

**Subcontract: (from 343-9374)**

**Salary**

faculty summer support - Jon Goodall  
graduate student

**Fringe**

faculty summer support - Jon Goodall  
graduate student

tuition

USC indirect costs

**Total Subcontract**

**Subtotal**

**MTDC**

**Indirect Costs**

**Grant Total**

(b) (4), (b) (6)  
(b) (6)  
  
3,203  
2,326 3,441 5,031 5,696 5,867  
10,819 11,264 16,466 18,642 19,200

(b) (4), (b) (6)

387,480 422,492 446,041 527,404 521,151





Nigel Fields/DC/USEPA/US

02/27/2008 06:19 PM

To Trish McMillan <trish306@duke.edu>

cc mmiranda@duke.edu

bcc

Subject Re: Jon Goodall - subcontract on SCEDDBO□

Hello Trish,

Regarding EPA grant RD 833293, I approve a new subcontract with University of South Carolina in order to facilitate the continued contribution of Dr. Jon Goodall to the Southern Center on Environmentally-Driven Disparities in Birth Outcomes. I am encouraged to hear that Dr. Goodall continues to communicate regularly with the Duke Center's staff, particularly the GISSA Core. I have confidence in the facility resources available to Dr. Goodall at USC. I understand the current year subcontract is (b) (6). Unless otherwise advised, I approve the proposed remaining out years as well (b) (6).

Kind Regards

Nigel A. Fields, M.S.P.H.  
Environmental Health Scientist  
202.343.9767

=====

For US Postal correspondence, please use:

US EPA,  
National Center for Environmental Research (8723F)  
Washington, DC 20460

=====

For courier service, please use:

US EPA, Woodies Bldg, Room 3316  
1025 F Street, NW  
Washington, DC 20004

Office of Research Support  
Duke University

Campus Box 104010  
Durham, North Carolina 27708  
Telephone (919) 684-3030  
Fax (919) 684-2418

Suite 710 Erwin Square  
2200 West Main Street  
Durham, North Carolina 27705

March 7, 2008

Nigel A. Fields, M.S.P.H.  
US EPA,  
National Center for Environmental Research (8723F)  
Washington, DC 20460

Dear Mr. Fields:

On behalf of Duke University, I am pleased to endorse the enclosed proposal submitted by Professor Marie Lynn Miranda entitled "*Southern Center on Environmentally-Driven Disparities in Birth Outcomes (Supplement)*" requesting a total budget of \$98,350.

This office acts as the University's authorized official in approving and signing off on proposals. When a proposal is submitted, and if it is funded this office acts on behalf of Duke University faculty and fellows in negotiating and administering the award, insuring responsible accounting procedures, and notifying faculty and fellows of reports required by the sponsor.

Any technical questions about this project should be addressed to Dr. Miranda. But, in order to facilitate a response to any administrative questions related to this proposal, or to process an award should you decide to make one, please send all award and administrative correspondence to this office at the following address:

Judith Dillon, Director - Office of Research Support  
Duke University  
Suite 710 Erwin Square  
2200 West Main Street  
Durham, NC 27705

Please feel free to contact me if you require any additional information about Duke University. Your consideration of this proposal is greatly appreciated.

Sincerely,

(b) (6)

Maria Scripa, CRA  
Assistant Director

# APPLICATION FOR FEDERAL ASSISTANCE

<b>1. TYPE OF SUBMISSION:</b> Application <input type="checkbox"/> Construction <input checked="" type="checkbox"/> Non-Construction Preapplication <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		<b>2. DATE SUBMITTED</b>	Applicant Identifier														
		<b>3. DATE RECEIVED BY STATE</b>	State Application Identifier														
		<b>4. DATE RECEIVED BY FEDERAL AGENCY</b>	Federal Identifier														
<b>5. APPLICANT INFORMATION</b>																	
Legal Name: Duke University		Organizational Unit: Nicholas School of the Environment and Earth Sciences															
Address (give city, county, State, and zip code): 2200 West Main Street Suite 710 Durham, NC 27705-4010		Name and telephone number of person to be contacted on matters involving this application (give area code) ADMIN: Judith B. Dillon                      PI: Marie L. Miranda (919) 684-3030                                      (919) 613-8023															
<b>6. EMPLOYER IDENTIFICATION NUMBER (EIN):</b> <div style="border: 1px solid black; padding: 2px; display: inline-block;">             5 6 — 0 5 3 2 1 2 9           </div>		<b>7. TYPE OF APPLICANT: (enter appropriate letter in box)</b> <div style="text-align: right; margin-right: 20px;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;">J</div> </div> <table style="width: 100%; font-size: small;"> <tr> <td>A. State</td> <td>H. Independent School Dist.</td> </tr> <tr> <td>B. County</td> <td>I. State Controlled Institution of Higher Learning</td> </tr> <tr> <td>C. Municipal</td> <td>J. Private University</td> </tr> <tr> <td>D. Township</td> <td>K. Indian Tribe</td> </tr> <tr> <td>E. Interstate</td> <td>L. Individual</td> </tr> <tr> <td>F. Intermunicipal</td> <td>M. Profit Organization</td> </tr> <tr> <td>G. Special District</td> <td>N. Other (Specify) _____</td> </tr> </table>		A. State	H. Independent School Dist.	B. County	I. State Controlled Institution of Higher Learning	C. Municipal	J. Private University	D. Township	K. Indian Tribe	E. Interstate	L. Individual	F. Intermunicipal	M. Profit Organization	G. Special District	N. Other (Specify) _____
A. State	H. Independent School Dist.																
B. County	I. State Controlled Institution of Higher Learning																
C. Municipal	J. Private University																
D. Township	K. Indian Tribe																
E. Interstate	L. Individual																
F. Intermunicipal	M. Profit Organization																
G. Special District	N. Other (Specify) _____																
<b>8. TYPE OF APPLICATION:</b> <input checked="" type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es) <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block; vertical-align: middle;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block; vertical-align: middle;"></div> <table style="width: 100%; font-size: x-small;"> <tr> <td>A. Increase Award</td> <td>B. Decrease Award</td> <td>C. Increase Duration</td> </tr> <tr> <td>D. Decrease Duration</td> <td colspan="2">Other(specify): _____</td> </tr> </table>		A. Increase Award	B. Decrease Award	C. Increase Duration	D. Decrease Duration	Other(specify): _____		<b>9. NAME OF FEDERAL AGENCY:</b> Environmental Protection Agency									
A. Increase Award	B. Decrease Award	C. Increase Duration															
D. Decrease Duration	Other(specify): _____																
<b>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</b> <div style="border: 1px solid black; padding: 2px; display: inline-block;">             — — — — —           </div> TITLE: _____		<b>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</b> Southern Center on Environmentally-Driven Disparities in Birth Outcomes (Supplement)															
<b>12. AREAS AFFECTED BY PROJECT (Cities, Counties, States, etc.):</b> _____																	
<b>13. PROPOSED PROJECT</b>		<b>14. CONGRESSIONAL DISTRICTS OF:</b>															
Start Date 9/1/08	Ending Date 8/31/09	a. Applicant 04															
<b>15. ESTIMATED FUNDING:</b>		<b>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</b>															
a. Federal	\$ 98,350 <sup>00</sup>	a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:  DATE _____															
b. Applicant	\$ 0 <sup>00</sup>	b. No. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E. O. 12372 <input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW															
c. State	\$ <sup>00</sup>	<b>17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?</b> <input type="checkbox"/> Yes    If "Yes," attach an explanation. <input checked="" type="checkbox"/> No															
d. Local	\$ <sup>00</sup>	<b>18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.</b>															
e. Other	\$ <sup>00</sup>	c. Telephone Number (919) 684-3030															
f. Program Income	\$ <sup>00</sup>	e. Date Signed															
g. TOTAL	\$ 98,350 <sup>00</sup>																
a. Type Name of Authorized Representative Judith B. Dillon		b. Title Director															
d. Signature of Authorized Representative		c. Telephone Number (919) 684-3030															



# BUDGET INFORMATION - Non-Construction Programs

OMB Approval N 348-0044

## SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		\$	\$	98,350	0	98,350
2.						
3.						
4.						
5. Totals		\$	\$	98,350	0	98,350

## SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1)	(2)	(3)	(4)	
a. Personnel	\$ (b) (4), (b) (6)	\$	\$	\$	\$ (b) (4), (b) (6)
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges (sum of 6a-6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	\$ 98,350	\$	\$	\$	\$ 98,350
7. Program Income	\$	\$	\$	\$	\$

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SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	\$ 0	\$	\$	\$ 0
9.				
10.				
11.				
12. TOTAL (sum of lines 8-11)	\$ 0	\$	\$	\$ 0

  

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	\$ 98,350	\$ 24,588	\$ 24,588	\$ 24,588	\$ 24,586
14. Non-Federal	0	0	0	0	0
15. TOTAL (sum of lines 13 and 14)	\$ 98,350	\$ 24,588	\$ 24,588	\$ 24,588	\$ 24,586

  

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	\$	\$	\$	\$
17.				
18.				
19.				
20. TOTAL (sum of lines 16-19)	\$	\$	\$	\$

  

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges:	22. Indirect Charges: (b) (4)
23. Remarks: See Attached	

## BUDGET JUSTIFICATION

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### Budget Justification

Postdoctoral Associate - A postdoctoral associate will work closely with Drs. Miranda and Gelfand (investigators on the SCEDDBO parent grant) on developing hierarchical space-time statistical models to explore the effects of social and environmental factors on birth weight outcomes for pregnant women. S/he will work on this project from September 1, 2008 to August 31, 2009.

Fringe and cost of living - Fringe benefits are calculated at the standard Duke rate for research staff. An annual 3% cost of living raise, which is standardly implemented at the university on July 1 of each year, is included.

Travel - Funds are requested for travel by the postdoctoral associate to attend meetings and/or seminars for presentation of research results in the amount of \$1500 for the project period.

Indirect costs - The Duke University negotiated indirect cost rate is (b) (4)

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# DUKE UNIVERSITY

## Grant Application

Miranda, Marie L.

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### SUMMARY OF WORK

The supplemental award to the EPA Children's Center Grant, Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO), will be used to support the development of hierarchical space-time statistical models to explore the effects of social and environmental factors on birth weight outcomes for pregnant women. Statistical models will be developed to provide a coherent framework for fusing air pollution monitoring data and Community Multi-Scale Air Quality (CMAQ) model output. CMAQ is an atmospheric simulation model that is used to predict average pollution levels for gridded cells.

The primary research objective of SCEDDBO is to determine how environmental, social, and host factors jointly contribute to health disparities in health outcomes. One of the key issues here is to develop the best assessment of exposure to environmental stressors. In this regard, based upon earlier literature as well as animal experiments, we anticipate that exposure to fine and coarse particulate matter (PM) as well as ozone can affect birth outcomes - in particular, low birthweight and pre-term births. The problem we face is to develop an accurate assessment of such exposure during the course of a woman's pregnancy.

Currently, we are linking birth certificate data to air quality monitoring data by matching maternal residential address to the nearest Air Quality System (AQS) monitor. However, the nearest site may not provide representative air quality levels at individual addresses. A preferred approach is to combine both air monitoring data and CMAQ to provide optimal predictions of air quality at specific locations. Then these high resolution predictions of air quality can be applied to the Stochastic Human Exposure and Dose Simulation (SHEDS) model to provide optimal simulated human exposures to ozone and PM. These simulated human exposures are expected to provide much better assessments of exposure - birthweight relationships. The proposed additional funding will be used to develop highly refined space-time exposure models for PM and ozone, using SHEDS modeling approaches. These models will be applied to both the population-level data and prospective cohort study data.

We have PM and ozone measurements available daily from AQS monitoring stations. First, we will fit space-time models to these datasets and then interpolate space-time surfaces to achieve daily, perhaps weekly exposure at given residence locations. A second, more sophisticated approach, will adopt a data assimilation strategy. In this regard, we have modeled PM and ozone available at very high temporal resolution over 12 km grid cells (provided by CMAQ). We will fuse the station data and the model output to learn about the true unobserved exposure surface. Again, this would be implemented over space and time, enabling space-time interpolation to residence locations. In addition to the existing more standard approaches, a third new and attractive strategy is a space-time down-scaler model. Here, the notion is that there is a relationship between the observed station data and the corresponding CMAQ model output. However, this relationship may vary in space and time. In other words, the calibration of the CMAQ data to the station data requires a rather sophisticated model. However, once we achieve space-time calibration, then we can down-scale CMAQ grid cell values in time and space, again enabling interpolation to exact residence locations.

The supplemental award to the SCEDDBO center grant will be used in direct conjunction with Projects A (spatial epidemiology) and B (clinical obstetrics), and indirectly support the work being undertaken in Project C. Through investigation of the above approaches, we expect to achieve the most reliable prediction of ambient PM and ozone exposure yet developed, as well as the uncertainty associated with these predictions. Through a hierarchical model, we will insert these predictions into the SHEDS model and propagate uncertainty through the modeling stages. Thus, we

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**DUKE UNIVERSITY**

Grant Application

Miranda, Marie L.

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will estimate individual exposures with associated uncertainty, allowing for much improved assessment of the impact of exposures on pregnancy outcomes. The new exposure estimates will be directly relevant to the analysis of pregnancy outcomes in Projects A and B and will be used to calibrate exposure levels in Project C (animal model). Thus the supplement will be highly additive and synergistic with the existing work of SCEDDBO and advance the state-of-science for predicting air quality surfaces using different sources of spatial information such as site-specific air monitoring data and gridded numerical model output.